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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,707	10/14/2003	Gregory Kellogg	95,1408-TTT	4837

EXAMINER	
WRIGHT, PATRICIA KATHRYN	

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/684,707	Applicant(s) KELLOGG ET AL.	
	Examiner P. Kathryn Wright	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 16-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/25/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II, claims 9-15, in the reply filed on July 06, 2007 is acknowledged. The traversal is on the ground(s) that the additional inventions do not constitute an undue burden on the Examiner since Groups I-III are classified in the same class and subclass.
2. This is not found persuasive because there would be a serious burden on the examiner if restriction is not required. As set forth in the restriction requirement, mailed June 07, 2007, the examiner the inventions of Groups I to III are distinct and would require different fields of search. That is, the search for one of the inventions is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes /subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together). Patents need not be cited to show different fields of search. See MPEP 808.02 [R-5].

The requirement is still deemed proper and is therefore made FINAL.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

6. The disclosure of the prior-filed application, Application No. 09/083,678 (now US Patent no. 6,063,589), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the prior filed application does not provide adequate support for limitation (f) in independent claim 9, i.e., a read window manifold comprising a series of chambers separated by septa and arranged linearly and adjacently on the surface of the platform away from the position of the fluid connection of the manifold with the fifth microchannel.

Accordingly, claims 9-15 are not entitled to the benefit of the prior application and the effective filing date of the instant invention is May 19, 1999. If applicant disagrees,

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applicant is hereby invited to provide the area of support for claim limitations within the prior nonprovisional application.

### ***Information Disclosure Statement***

7. The information disclosure statement filed June 25, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Drawings***

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first microchannel, second microchannel, third microchannel, fourth microchannel, fifth microchannel, sixth microchannel, depression in the entry port, mixing chamber, first metering portion of the secondary metering chamber, second overflow portion of the secondary metering chamber, septum that extends from a position in the chamber farthest from the center of rotation, chamber wall, septa, read window manifold (claim 9), and heating element in thermal contact with the sacrificial valve (claim 13) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 950 (page 53 of specification).
10. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "922" has been used to designate both "secondary metering structure" and "boronate affinity matrix chamber", see page 54 of specification.
11. The drawings are objected to under 37 CFR 1.83(a) because Fig. 15 fails to show the details as described in the specification at page 19. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).
12. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

13. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

14. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: entry port depression having a volumetric capacity of about 1 to 150 microliters (note that the specification supports the *metering section* having a volumetric capacity of about 5 to 150 microliters at page 51), the first microchannel, second microchannel, third microchannel, fourth microchannel, fifth microchannel, sixth microchannel, mixing chamber (note specification does disclose a blood lysis chamber 915), first metering portion of the secondary metering chamber, second overflow portion of the secondary metering chamber, and read window manifold.

15. The disclosure is objected to because of the following informalities: the DESCRIPTION OF THE DRAWINGS section at page 7 does not address each Figure, e.g. Fig. 1A-1B, 2A-E, 3A-E, etc. Also, the specification makes reference to Fig. 11 at page 53. Furthermore, there is no Fig. 11, rather Figs. 11A-J.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9 and elsewhere in the claims, "capillary microchannel" and "capillary" and "microchannel" are indefinite because applicant has not provided a clear definition of the metes and bounds of these terms. On page 8, lines 11-13, applicant states that the terms "capillary", "microchannel" and "microcapillary" are interchangeable. It is therefore unclear how "capillary microchannel" differs from "capillary". Further, there is no clear definition of the dimension(s) that distinguish a microchannel from a channel. On page 14, lines 3-4, the depth of a microchannel appears to range from less than 500-800 micrometer up to 90 mm (90% of the 100 mm platform thickness). On page 15, the metering capillary has a "square cross-sectional diameter" (is that the side or diagonal of the square?) of 0.02 mm to 2.0 cm. Numerous other exemplary ranges are found throughout the text. No clear definition is provided.

Claim 9, item d) line 6, recites "a septum that extends...to a position just short of a chamber wall". The phrase "just short" is confusing and indefinite. It is not clear from the claims how "short" the septum is from the chamber wall. Clarification is requested.



Claim 9 also recites "the separation chamber" in item e) line 3. There is insufficient antecedent basis for this limitation in the claim. This limitation should be changed to "the analyte separation assay chamber" for consistency.

### ***Allowable Subject Matter***

18. Claims 9-15 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

19. The following is a statement of reasons for the indication of allowable subject matter. The prior art fails to teach or suggest a microfluidic rotor having a port, mixing chamber, secondary metering chamber, analyte separation chamber and read window manifold as claimed, wherein the second metering chamber comprises a first metering portion and a second overflow portion separated by a septum and a read window manifold comprising a series of chambers separated by septa and arranged linearly and adjacently on the surface of the platform away from the position of the fluid connection of the manifold with the fifth microchannel.

### ***Conclusion***

20. Claims 9-15 are currently rejected.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 22, 2007

pkw

  
Jill Warden  
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